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Rule  
105  
8/21/07

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In re Application of:  
Todd K. Whitehurst et al.  
Serial No. 10/731,551  
Filed: December 8, 2003  
Docket:

DECISION ON PETITION  
UNDER 37 CFR § 1.181

Title: FULLY IMPLANTABLE  
MINIAUTURE  
NEUROSTILULATION FOR  
INTERCOSTAL NERVE  
STIMULATION AS A THERAPY FOR  
ANGINA PECTORIS

This is a decision on the petition filed March 19, 2007 petitioning the Technology Center Director under 37 CFR § 1.181 for supervisory review of the requirement under 37 CFR § 1.105. No fee is due.

The petition is dismissed.

Background

In the Office Action on May 18, 2006, under the Section, "Response to Arguments," Examiner told Applicants that he wanted to know:

...what nerves the applicant considers the intercoastal nerve branches to consist of. Specifically, the names of the nerves (such as the lateral cutaneous branch, anterior cutaneous branch, etc), whether these branches are directly connected to the intercoastal nerves, and whether they are connected toward or away from the spine. This information is required to extend the domain of search for prior art.

In a response filed on August 18, 2006, Applicants respectfully declined to define on the record the term, "intercostal nerve branches."

On September 18, 2006, Examiner mailed a 37 CFR § 1.105 requirement to Applicants requiring Applicants to state on the record the definition of "intercostal nerve branches."

Examiner justified request by stating,

The information is required to extend the domain of search for prior art... to establish the level of knowledge of those of ordinary skill in the claimed subject matter art of applying stimulation to the intercostal nerve branches and intercostal nerves.

In a November 17, 2006 response, Applicants stated that Examiner's reason for the 37 CFR § 1.105 Requirement, "extending the domain of search for prior art," fell outside the scope of 37 CFR § 1.105 because it "requires introduction of new matter into the application and unnecessary prosecution history estoppel to the detriment of Applicant." Furthermore, Applicant submitted that request was *not* listed as one of the examples under 37 CFR § 1.105 pertaining to the types of information that may be requested by an Examiner.

Applicants further emphasize, through case law, that the Office must give each claim its plain and ordinary meaning in the relevant art unless the specification clearly provides an alternative definition.

...claim terms should be given *'their broadest reasonable construction* in light of the specification as it would be interpreted by one of ordinary skill *the art.*" (emphasis added). *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (citing *In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004):

Applicants argue that providing any other definition would be introducing, "new matter into the application to the extent that such definition would be used to supplement or supersede the specification in construing the relevant claim terms."

On March 19, 2007 Applicants petitioned 37 CFR § 1.105 Requirement.

### Discussion and Analysis

With respect to the introduction of new matter, MPEP 2163.06, "Relationship of Written Description Requirement to New Matter," states, in part:

Lack of written description is an issue that generally arises with respect to the subject matter of a claim. If an applicant amends or attempts to amend the abstract, specification or drawings of an application, **an issue of new matter will arise if the content of the amendment is not described in the application as filed. [Emphasis added]**

In the instant case, Applicants are not being required to insert any materials into the disclosure. Therefore, new matter cannot be introduced into the disclosure.

With respect to Applicants' assertion of unnecessary prosecution history estoppel, Applicants are being required to provide information in accordance with the regulations of 37 CFR § 1.105. All communications are, of course, part of the record.

With respect to Applicants' argument that none of the examples listed within 37 CFR § 1.105 mention, "requiring an Applicant to give a supplemental definition to a claim term," it is to be noted that use of the term "for example" and the providing of examples under 37 CFR § 1.105 are intended not to be restrictive but to provide guidance to other possibilities that may fit the application being reviewed.

MPEP 704.11(a), "Examples of Information Reasonably Required," specifies:

37 CFR § 1.105(a)(1)(i)-(viii) lists specific examples of information that may be reasonably required. Other examples, **not meant to be exhaustive**, of information that may be reasonably required for examination of an application include...[Emphasis added]

Furthermore, Federal Circuit Court allows an Examiner to request a definition of a term within a 37 CFR § 1.105 Request:

Scope of information that may be required from applicant by patent examiner pursuant to 37 C.F.R. §1.105 encompasses information relevant to patent examination either procedurally or substantively, and includes zone of information beyond that defined by 37 C.F.R. §1.56 as material to patentability, and beyond that which is directly useful to support rejection or conclusively decide issue of patentability, since Section 1.105(a)(1) states that PTO may "require the submission ... of such information as may be reasonably necessary to properly examine or treat the matter". *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 73 USPQ2d 1409 (Fed. Cir. 2005).

United States Patent and Trademark Office can use requirement for information under 37 C.F.R. §1.105 to compel disclosure of information that patent examiner deems pertinent to patentability, even if applicant disagrees with examiner concerning significance of information to ultimate question of whether application discloses patentable subject matter, since PTO is clearly entitled to use Section 1.105 to seek information that may support rejection, and since examiner is charged with duty of deciding whether patent should issue from application, and so long as examiner's request for information is not arbitrary or capricious, applicant cannot impede examiner's performance of that duty by refusing to comply with information requirement that proceeds from examiner's view of scope of law to be applied to application. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 73 USPQ2d 1409 (Fed. Cir. 2005).

In the instant case, a review of the claimed/disclosed application indicates that Applicants have not indicated what nerves the Applicants consider the intercostal nerve branches as comprising. The terms, "intercostal nerves" or "intercostal nerve branches," apparently, can comprise different nerve branches at different locations. Thus, the need for more information to define these terms. If Applicants are stating that the claimed/disclosed treatment will work equally well when the neurostimulator is placed adjacent to any intercostal nerves influencing the angina pectoris, this is not at all clear from the filed disclosure or presently accumulating record. Is there an intercostal nerve set or branch that is more sensitive to the disclosed treatment than others? If so, Applicants have not stated this. Applicants are reminded that 35 U.S.C. 112, first paragraph, requires disclosure of the best mode. It is not clear that this is present or needs to be if all the intercostal nerve branches work the same. However, this should be part of the

examination process and may be determinable by the submissions, if any, as being required by Applicants.

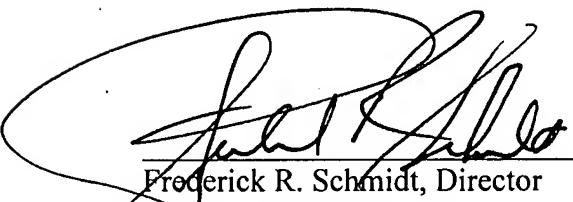
Conclusion

Ultimately, the purpose in requiring Applicants to identify what nerves the Applicants consider the intercostal nerve branches to comprise is to improve the quality of the examination of the application. In view thereof, Examiner's requirement is not seen as unreasonable and is seen as within the scope of 37 CFR § 1.105.

PETITION DISMISSED.

Petitioner may file a request for reconsideration of this decision, without fee. However, such request must be filed within two months of the date of this decision. Petitioner is reminded that the mere filing of the request will not stay any period for reply that may be running against the application, nor act as a stay of other proceedings. See 37 CFR § 1.181(f).

Any inquiry regarding this decision should be directed to Allan N. Shoap, Special Program Examiner, at (571) 272-4514.



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Frederick R. Schmidt, Director  
Technology Center 3700